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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/718,846	11/21/2003	Rima Kaddurah-Daouk	AVZ-001CPUSCN	1479

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EXAMINER	
SHIBUYA, MARK LANCE	

ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 04/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/718,846	KADDURAH-DAOUK ET AL.	
	Examiner	Art Unit	
	Mark L. Shibuya	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 March 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) *3-6 and 9-12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1.2, 7 and 8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/1/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-12 are pending. Claims 3-6 and 9-12 are withdrawn as drawn to a non-elected invention and species. Claims 1, 2, 7 and 8 are examined.

Election/Restrictions

2. Applicant's election without traverse of Group I, claims 1-2 and 7-8, in the reply filed on 3/4/2005, is acknowledged.

3. Claims 3-6 and 9-12 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 3/4/2005.

Priority

4. This application is a continuation of 08/853,174, filed 5/7/1997, now US 6,706,764; which is the national stage of PCT/US95/14567, filed 11/7/1995; which is a continuation of 08/336,388, filed 11/8/1994, now abandoned.

Information Disclosure Statement

5. The information disclosure statement filed 10/01/2004 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because cite no. F2 does not provide

a date of publication. It has been placed in the application file, but in regard only to cite no. F2, the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1, 2, 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jennings, WO 94/17794 (8/18/1994; IDS filed 10/1/2004, cite no. A10), in view of Coffin, US 5,492,930 (2/96; filed 4/94; IDS filed 10/1/2004, cite no. A4).

The claims are drawn to methods for treating a subject afflicted with amyotropic lateral sclerosis, comprising administering to the subject an amount of creatine or creatine phosphate, such that the subject is treated for amyotropic lateral sclerosis; and wherein the subject is human.

Jennings teaches compositions comprising amounts of creatine and creatine phosphate (e.g., see creatine and glycine derivative I, where Y is H_2PO_3), for use in treating wasting diseases, such as multiple sclerosis; and dementias, such as Alzheimer's disease. See Abstract; pages 3-5 and claims. Jennings, at p. 2, teaches that creatine derivatives blended with one or more sugars can enhance tissue formation in animals. Jennings, at p. 3, teaches the treatment of wasting disease by the administration of creatine-containing compositions, and contemplates enhancing tissue formation in diseased cardiac muscle.

The Jennings reference differs from the presently claimed invention by failing to specifically teach the use of creatine, or creatine phosphate, to treat amyotropic lateral sclerosis (ALS).

Coffin teaches that Alzheimer's, as well as ALS, are members of a class of CNS neurodegenerative diseases with common etiology (e.g., changes in excitatory amino acid transmission) and symptoms (e.g., reduced cognitive ability, e.g., dementia) and thus are often similarly treated. See, e.g., Coffin at col. 1.

It would have been prima facie obvious to one of ordinary skill in the art at the time of applicant's invention to use the Jennings' creatine, or creatine phosphate, compositions to treat ALS, because Jennings teaches the general treatment of dementia and Alzheimer's disease and the Coffin reference indicates that drugs for treating dementia are useful in treating related neurodegenerative disorders (e.g., related by etiology and or symptoms), such as Alzheimer's dementia.

Accordingly, one of ordinary skill in the art would be motivated to utilize creatine, or creatine phosphate, to treat ALS, in addition to dementia and Alzheimer's, as taught by Jennings, because these disease states share common etiology and/or symptoms, as disclosed in the Coffin reference.

7. Claims 1, 2, 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jennings, WO 94/17794 (8/18/1994; IDS filed 10/1/2004, cite no. A10), in view of Flohe et al., US 4,788,179 (11/1988; filed 12/1985).

The claims are drawn to methods for treating a subject afflicted with amyotropic lateral sclerosis, comprising administering to the subject an amount of creatine or creatine phosphate, such that the subject is treated for amyotropic lateral sclerosis; and wherein the subject is human.

Jennings teaches compositions comprising amounts of creatine and creatine phosphate (e.g., see creatine and glycine derivative I, where Y is H_2PO_3), for use in treating wasting diseases, such as multiple sclerosis; and dementias, such as Alzheimer's disease. See Abstract; pages 3-5 and claims. Jennings, at p. 2, teaches

that creatine derivatives blended with one or more sugars can enhance tissue formation in animals. Jennings, at p. 3, teaches the treatment of wasting disease by the administration of creatine-containing compositions, and contemplates enhancing tissue formation in diseased cardiac muscle.

The Jennings reference differs from the presently claimed invention by failing to specifically teach the use of creatine, or creatine phosphate, to treat amyotropic lateral sclerosis (ALS).

Flohe et al., US 4,788,179, at col. 1, lines 8-22, teach that ALS causes the muscles to waste away, so that although the patient's intellect remains clear, the patient is trapped, by the disease's degenerative process, in an increasingly useless, dying body. Flohe et al., at Example 2, col. 5, for example, teaches the use of a peptide mendicant that resulted in an improvement in muscle weakness in an ALS patient, thereby allowing him some measure of temporary independence in everyday life.

It would have been *prima facie* obvious, at the time the invention was made, for one of ordinary skill in the art to have made used methods of treating humans afflicted with amyotropic lateral sclerosis (ALS) by administering an effective amount of creatine or creatine phosphate.

One of ordinary skill in the art would have been motivated to use methods for treating ALS, because the reference of Jennings teaches that creatine and creatine phosphate may be used to treat wasting disease, including wasting disease that affects muscle (such as cardiac muscle), and because Flohe et al., teach that treating the

muscle wasting of ALS patients can result in a temporary improvement in the everyday life of the patient.

One of ordinary skill in the art would have had a reasonable expectation of success in ameliorating muscle wasting, as in ALS, because Jennings teaches that creatine and creatine phosphate compositions are effective in treating wasting disease.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1, 2, 7 and 8 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 7, 8, and 13 of copending Application No. 10/718,765. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method for

treating a subject afflicted with amyotropic lateral sclerosis, comprising administering to the subject an amount of creatine (as in claim 1) or creatine phosphate (as in claim 2), such that the subject is treated for amyotropic lateral sclerosis, is anticipated by the method for treating a subject afflicted with a nervous system disease comprising administering to the subject an amount of creatine, creatine phosphate or a creatine analog or a salt thereof compound sufficient to prevent, reduce ameliorate or eliminate the disease. Claim 3 of the '765 application recites that the subject is a human, as in claims 2 and 8 of the instant claims. The '765 application, in the abstract, defines nervous system disease to include amyotropic lateral sclerosis.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

9. Claims 1, 2, 7 and 8 are rejected.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark L. Shibuya whose telephone number is (571) 272-0806. The examiner can normally be reached on M-F, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mark L. Shibuya
Examiner
Art Unit 1639

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